

U.S. NUCLEAR REGULATORY COMMISSION

Date: 8/1/06

TELEPHONE CONVERSATION RECORD

Time: 17:00

Mail Control 139062 License No(s). 07-12153-02 Docket No(s). 03001303
or Report No(s).

Name of Licensee: Christiana Care Health System

Name of Participant(s): Dr. Larry Simpson, Ph.D.
Randolph C. Ragland, Jr., NRC Region I

Telephone No. 302-545-3870

Subject: Christiana Care: Request for Additional Information
(NOTE: This will be used as the Documents Title in ADAMS)

Summary:

Dr. Simpson,

In support of your June 29, 2006, license amendment request, please provide the following information:

1) Your amendment request letter dated June 29, 2006, requested an amendment to NRC License No. 07-12153-02, to add Jon Strasser, M.D. as an Authorized User under 35.400 [i.e., Manual Brachytherapy]. In our 8/1/2006, telephone conversation, you stated that you actually had intended to have Dr. Strasser added as an authorized user for the same materials and uses listed on your license (i.e., 35.400; Yttrium 90 SIRspheres; Iodine 125 for use in the GliaSite RTS System; Iridium 192 in a remote afterloading brachtherapy device).

Please confirm that you are requesting Jon F. Strasser, MD to be added as an authorized user for 35.400; Yttrium 90 SIRspheres; Iodine 125 for use in the GliaSite RTS System; Iridium 192 in a remote afterloading brachytherapy device.

2) We are requesting a more specific preceptor statement for Dr. Strasser. You can either obtain a more specific preceptor statement signed by Dr. Jay Harris, Brigham and Women's Hospital, or you could have one of the physicians who is currently authorized on Christiana Care Health Services license No. 07-12153-02 sign a preceptor statement for Dr. Strasser.

Option 1: In your July 22, 2005, amendment request, you provided an attestation statement for Jon Strasser, M.D. from Jay Harris, M.D. The attestation statement is considered vague because it states that Jon Strasser, M.D. has achieved a level of competency sufficient to function independent as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status.

In addition, although you provided in your June 29, 2006, amendment request documentation that Jay Harris, MD is listed on the Commonwealth of Massachusetts, Agreement Broad Scope License #44-0004, Permit #900, it was not clear that Dr. Harris was authorized for high dose rate remote afterloaders.

Please provide additional information that documents or confirms that Dr. Jay Harris is an Authorized User on Commonwealth of Massachusetts, Agreement BroadScope License #44-0004, Permit #900 and is authorized for 10 CFR 35.400 use and and Iridium 192 in a remote afterloading brachtherapy device, AND request Dr. Harris to re-submit a preceptor statement that specifically attests that Dr. Strasser has achieved a level of competency to function independently as an authorized user for 35.400 and Iridium 192 in a remote afterloading brachtherapy device.

OR

Option 2: Have a Physician that is a current authorized user on Christiana Care Health Services NRC License No. 07-12153-02 (e.g., Christopher Koprowski, M.D.) for the materials and uses for which Dr. Strasser is seeking authorization (e.g., 35.400; Yttrium 90 Sirspheres; Iodine 125 for use in the GliaSite RTS System; Iridium 192 in a remote afterloading brachtherapy device), review Dr. Strasser's qualifications, and sign and date a preceptor statement that attests that

"Dr. Strasser has achieved a level of competency to function independently as an authorized user for 35.400 and Iridium 192 in a remote afterloading brachtherapy device."

3) Please confirm that Dr. Strasser will receive vendor training in the use of microspheres and the microsphere delivery system prior to any independent clinical procedures using Yttrium-90 SIRspheres.

4) Please confirm that Dr. Strasser will receive vendor training in the use of Proxima Therapeutics' GliaSite RTS prior to any independent clinical procedures using I-125 Iotrex Liquid Brachytherapy Source in Proxima GliaSite Radiation Therapy System.

5) Please have a management representative sign the response, include Mail Control No. 139062, and fax your response to NRC Licensing Assistant Team at 610-337-5269.

Action Required: Dr. Simpson will gather the requested information, obtain a management signature, include Mail Control No. 139062, and fax the response to NRC at 610-337-5269.

Document Availability: Publicly Available Non-Publicly Available
 Non-Sensitive Non-Sensitive Copyright Sensitive Sensitive Copyright
 Immediate Release Normal Release Delay Release Date
Prepared & SUNSI Review Completed By: R. Ragland / RA / Date: 08/04/2006